BME 400 (Biomedical Engineering Design)

Fall 2009

Project #38: Heated Diagnostic Radiology Exam Table

FINAL REPORT

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Abstract

Clinical X-ray examinations sometimes require patients to remain still while laying on the exam table. A common patient complaint is that X-ray examination tables are uncomfortable; specifically they are too hard and too cold. Patient discomfort is undesirable because an uncomfortable patient is more prone to moving during a procedure. The objective of the client and our team is to create a device that can ensure patient comfort while preserving radiolucency and patient safety. The focus of our work is to create a device to modify the current hard laminate surface of the X-ray table through the addition of padding and heat. The designed device consists of an Indium Tin Oxide (ITO) layer deposited on a polyethylene substrate placed between two dielectric Kapton® sheets on top of polyethylene foam. To produce heat, conductive copper tape bus bars are used to uniformly run current across the surface of the ITO. A microcontroller-based control unit powers the device on and off so to maintain a chosen target temperature. Finally, the entire device is enclosed in a sanitary vinyl cover. The materials used, in addition to the original X-ray exam table, do not attenuate more than allowed by CFR-Federal Code of Regulations Title 21. Future work entails scaling up our design, thoroughly testing the safety of the design, and incorporating more uniform silver ink bus bars.

Problem Motivation

A common patient complaint is that X-ray examination tables are uncomfortable, i.e. they are too cold and hard. Patient discomfort is a problem because during procedures a patient may be more prone to move if uncomfortable. Patient movement during imaging does not allow proper image acquisition.

Background

Diagnostic Use of X-rays

X-rays are high-frequency electromagnetic waves produced when fast-moving electrons collide with substances in their path. X-rays are similar to visible light rays except that they have 1/10,000 the wavelength (Tsai, 2004). The short wavelength of X-rays allows them to penetrate very dense substances to produce images, or conversely shadows, that can be recorded on photographic film (Tsai, 2004) or digitally. X-ray imaging is useful diagnostically because density differences between various body structures produce images of varying intensity on the X-ray film (Tsai, 2004). Dense structures appear white, and air-filled or low-density areas of the body appear darker or black.

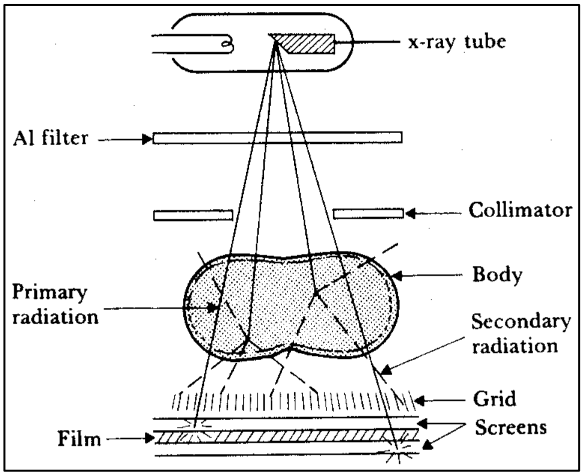

Figure 1: Simplified X-ray system

A simplified diagram of an X-ray system is shown above (Figure 1). Grids reject unwanted rays while phosphor screens emit many light photons for each X-ray photon, thus assisting in the contrast of the image and the darkening of the photographic film, respectively (Tsai, 2004). The X-rays are scattered in all directions from the source but, in order to prevent harm to the patient and technicians as well as increase resolution, they are directed by a collimator. The collimator directs the emission so that only the X-rays used to make the image are passed. Harmful low energy X-rays that are not capable of passing through a patient's body are stopped by an aluminum filter. Electrons are accelerated at +100 keV from the heated filament to the tungsten anode, consequently emitting X-rays (Tsai, 2004).

In medicine, X-rays have primarily been used to image the anatomy of the body. X-rays lack the capability to image flow and are not useful in imaging the physiology of the body. One of the most common uses of X-ray imaging is in the diagnosis of skeletal pathologies. According to our client, Lanee Maclean, the duration of a procedure can last from minutes to more than an hour. To preserve the integrity of the image it is necessary for the patient to remain still during acquisition.

Current X-Ray Examination Table

The examination table we are working with is shown below in Figure 2.

Figure 2: Continental X-ray Corporation "Classic Elevating 4-Way Float Top Table". (www.advanceimaging.net)

The exam table was described to us as generic by our client. Our client indicated that the design is commonly used by other manufacturers of tables. The table has a hard laminate surface where the patient lies during a procedure. Along the edges of the hard laminate surface are metal guide rails available for the attachment of medical instrumentation.

The top of the table is 2.2 m long and .8 m wide. The tabletop is capable of moving 1.14 m length-wise and 0.25 m transversely. The height of the table top is adjustable from 0.55 m at its lowest to 0.84 m at its highest. The maximum patient weight as specified by the manufacturer is 158 kg. The standby heat load of the table is 800 BTU per hour.

X-Ray Attenuation

X-ray attenuation is important in the design and construction of a heated radiological examination table because the attenuation of the materials within the path of the X-rays may affect the contrast of an X-ray image.

X-ray attenuation is characterized by the linear attenuation coefficient (μ) and relates to the radiolucency or radiopaqueness of a material. The linear attenuation coefficient is a property of the material and generally, materials composed of atoms with high atomic numbers will attenuate more than materials composed of atoms with low atomic numbers. The less a material attenuates upon excitement by an X-ray, the more radiolucent it will appear in an X-ray image.

The attenuation of a material is more often characterized as the mass attenuation coefficient (μ/ρ), which is simply the linear attenuation coefficient (μ) divided by the density of the material (ρ). It is important to note that mass attenuation coefficient varies with photon energy (Figure 3.). Typical photon energy ranges for diagnostic X-ray imaging are between 12.4 and 124 keV (Links, 2005), indicated by the red box in Figure 3.

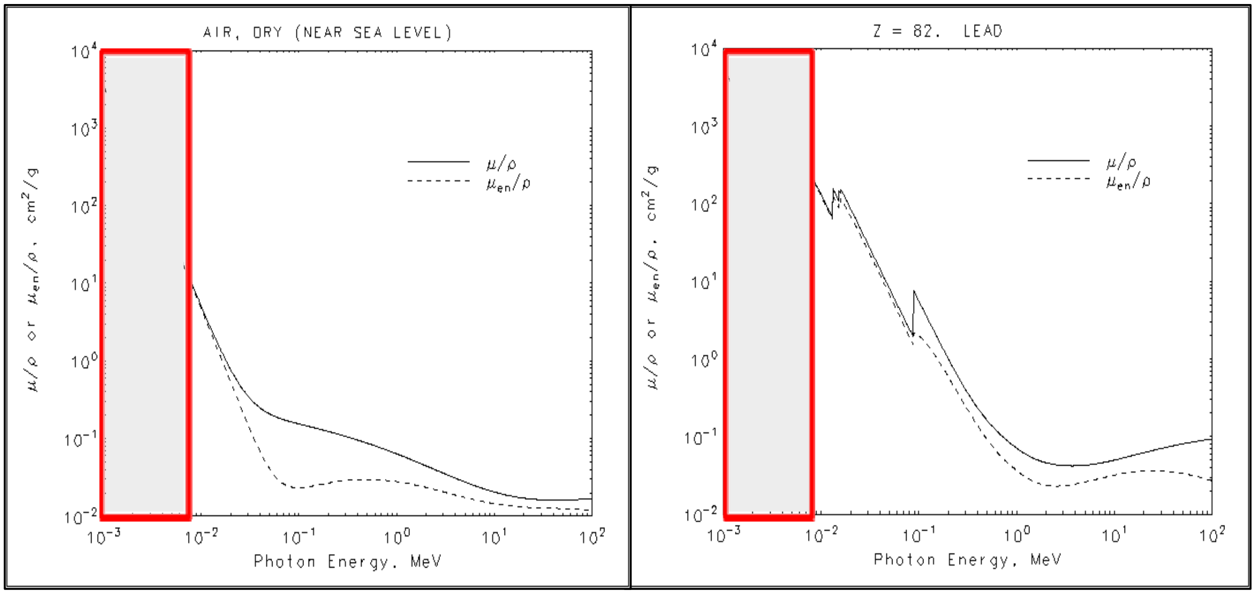

Figure 3: Mass Attenuation vs. Photon Energy for Air and Lead (http://physics.nist.gov/)

Upon examination of the mass attenuation vs. photon energy graphs in Figure 3, it is apparent that lead has discontinuities in its curve. These discontinuities are often called the K-edge or absorption edge. The K-edge represents the photoelectric absorption of photons by the lead atom. This phenomenon explains why lead is used to block X-rays whereas X-rays readily pass through other media, such as air. In other words, the K-edge is responsible for the radiopaqueness of a material. Therefore, using materials that lack a K-edge is essential for the success of a heated radiologic examination table.

Not only must the materials being used for the heated radiologic examination table lack a K-edge to prevent radiopaqueness, the materials must also attenuate such that they produce a uniform loss in intensity of the incident X-ray beam across the entire image (Vetter, J. Personal interview. 3/2/09). While some attenuation of the beam will be unavoidable, it is important that the materials attenuate homogenously, so as not to introduce any irregularities that may complicate diagnostics.

The percent loss of intensity of the incident X-ray beam can be calculated using Equation 1. What is important to note from this equation is that the percent loss of intensity of the incident X-ray beam is dependent on three different factors: the mass attenuation coefficient, thickness, and density of the material. Therefore, assuming different materials will be present within the imaging area of an X-ray, the densities and thicknesses of the various materials can be adjusted such that the percent loss of intensity of the incident X-ray beam is nearly uniform across the imaging area. This adjustment will thus eliminate any of the materials from appearing in the X-ray image due to differences in contrast.

Equation 1 (Links, 2005)

$$\left[1-\left(\frac{I}{I_O}\right)\right]\cdot 100 = e^{\left(-\left(\frac{\mu}{\rho}\right)*\Delta x\cdot\rho\right)}$$

Where:

$\left[1-\left(\frac{I}{I_O}\right)\right]\cdot 100$ = Percent loss of intensity of the incident X-ray beam
(μ/ρ) = Mass attenuation coefficient
Δx =Thickness of the material
ρ =Density of the material

Market

Currently, there is no product on the U.S. market capable of heating a patient during an X-ray examination. This makes our design novel and offers us the opportunity to fulfill a niche in the market. In the U.S. alone, there are over 5,815 registered hospitals nationwide (not including health clinics) that have at least one X-ray examination table (American Hospital Association, 2009). Annually in the United States there are over 90.6 million X-ray procedures performed where our device could be used (Bhargavan and Sunshine, 2005; and U.S. Census Bureau, 2001). Combined with dental, sports medicine, and veterinary fields, this untapped market is massive.

Design Constraints

The application of our device for use in X-ray or radiology procedures imposes several limitations on our design. A list of requirements and design constraints has been developed by our client; in addition our team has developed several of its own, and these are listed below.

I. **Radiolucency**: The most important constraint on our design is radiolucency. Our device must be almost completely radiolucent. It must not significantly attenuate the X-ray beam, and it must not introduce artifacts into the X-ray image. Contrast introduced into an image could render it useless in the diagnosis of certain pathologies, or possibly lead to the improper diagnosis of a certain disease state. During the design process we must consider how specific materials, temperatures, and geometries will affect the image. The design and development of the device will largely depend on the radiolucency of materials available.

II. **Patient Safety**: Patient safety is of high consideration. We must identify and eliminate the potential for patient burns or electrocution. We must make sure the surface that the patient will come into contact with is non-toxic and easily sanitized. Furthermore, this foam must not absorb any fluids that it comes into contact with. Ideally the padding used would be FDA approved for clinical use and sterilization.

III. **Heated Examination Surface**: Our device must provide a controllable, comfortable amount of heat to the patient. The operating temperature for the surface of the device should be 37 +/-5 degrees Celsius. Ideally, the amount of heat transferred to the patient would be adjustable within 1 degree Celsius. The heat applied should not exceed a physiologically safe value and should not be capable of burning the patient under any circumstances. This means the device must never approach 54 degrees Celsius (the lowest temperature at which skin burns can occur). The heat applied should have a relatively fast response to change (~60 seconds). Both the patient and the technician should have control of the temperature.

IV. **Cushioned Examination Surface**. The device must have lower rigidity than the current hard laminate surface.

V. **Anatomical Distortion:** It is important that our device does not alter the normal anatomy of the patient. X-rays are commonly used in imaging body anatomy, altering the patient anatomy could render the X-ray procedure useless for its intended purpose. Our design team must consider the anatomy of all patients that may possibly use the device and ensure that the rigidity of specific parts of the design do not interfere or alter the natural body configuration.

VI. **Obstruction of Technician's Workspace:** The size of the device must be limited in that it must not obstruct with the workspace of the X-ray technician.

Resistive Heating

Rather than taking a mechanical approach towards generating the heat necessary for our design, our team decided to pursue a solid-state resistive heating design. However, identifying a resistive heating element that is undetectable under normal X-ray image analysis is not trivial. Therefore, the heating element was deemed the most critical aspect of designing a heated X-ray examination pad. Materials considered for resistive heating include: indium tin oxide (ITO) films, polyimide films, polyaniline dipped nylons, and carbon fiber.

Indium Tin Oxide (ITO) films

Indium Tin Oxide (ITO) films are commonly used as a translucent heating element (e.g. for heating liquid crystal displays in cold environments). ITO surface heaters are commercially available. ITO films are produced through a sputtering process, which results in a thin (~100 nm) film of ITO on a surface such as polyethylene, or (more commonly) glass. The sputtering process results in a uniform layer of ITO deposited on the film surface; consequently, heating is also uniform. The resistance of ITO heaters is customizable by changing the thickness of the sputtered ITO layer. Because the conducting ITO is coated on the surface of the film, it is susceptible to degradation by bending, rubbing, or other mechanical stresses.

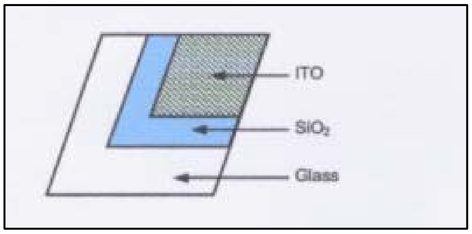

Figure 4: ITO Chemical Composition
(http://www.visionteksystems.co.uk/)

Polyimide Films

Kapton® RS polyimide film is produced and commercially available from DuPont®, a company with a long standing reputation for high quality products. Kapton® is stable up to 350 degrees Celsius and provides even heating. Kapton® is thin (~0.5 mm) and flexible. It can be produced in large, continuous sheets at user-specified widths. Kapton® degrades when exposed to ultraviolet light in the presence of moisture or high humidity. The degradation of Kapton® when exposed to X-ray radiation is unknown.

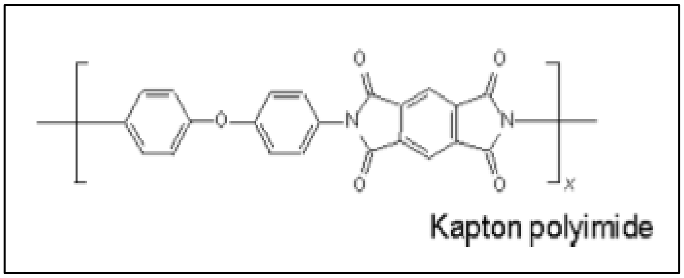

Figure 5: Kapton® Chemical Composition.
(http://www.dupont.com/)

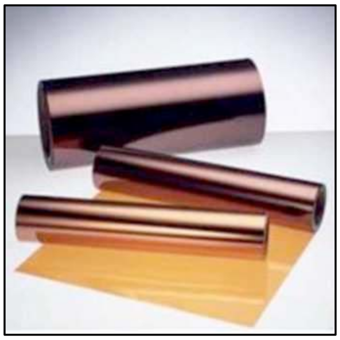

Figure 6: Kapton®
(http://www.dupont.com/)

Polyaniline Dipped Nylons

EEONFELT® is a conducting polyaniline dipped nylon felt fabric manufactured by the Eeonyx® Company. This material provides even heating and has an adjustable resistivity. By altering the concentration of polyaniline that the material is dipped in, surface resistance can be varied between 20 ohm/square to 10^6 ohm/square. Because the material is made from nylon felt it is very flexible. This material is relatively new to the field of surface heaters and commercial availability is limited. Because it is relatively new technology, it degradation when exposed to high energy radiation such as X-rays is unknown.

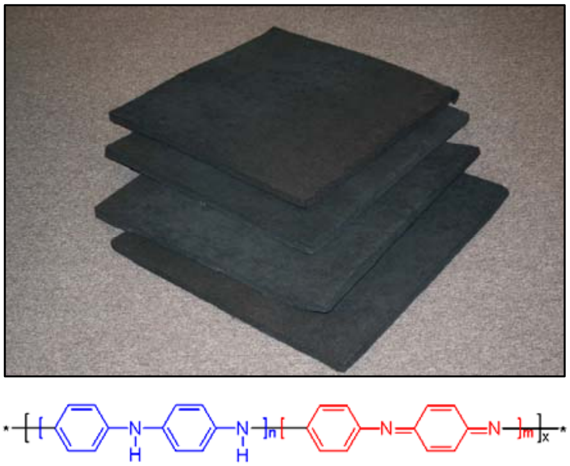

Figure 7: EEONFELT and its Chemical Composition.
(http://www.eeonyx.com)

Carbon Fiber

Carbon fiber heating strips are commercially available. Several companies manufacture carbon fiber heating elements for radiant floor heating and other applications. The thickness of these elements can be less than 0.4 mm and do not degrade when subjected to X-ray radiation, however they have limited flexibility. These elements have proven to be safe, and because of their uniform composition, have been shown to heat uniformly. The width of strips is on the order of inches, and does not approach the width or length of an X-ray exam table. The maximum temperature of these elements is around 28 degrees Celsius.

Figure 8: Carbon Fiber Strips
(http://www.handyheat.co.uk/)

Design Matrix

Criteria	Weight	ITO Film	Kapton®	EEONFELT	Carbon Fiber
Uniformity	30	30	30	30	20
Heating	30	25	20	25	15
Radiolucency	30	25	25	20	20
Cost	10	7	8	5	7
TOTAL	100	87	83	80	62

Since heating the table without unacceptably attenuating the beam or introducing artifacts in the image was our primary concern, our design matrix centered on choosing the appropriate material for the heating element. After four candidates were identified, they were evaluated based on four criteria: homogeneity, radiolucency, heating capability, and cost. Having learned from our experiences last semester, we made uniformity as important as radiolucency and heating. All three of these criteria were non-negotiable; our design could not be successful if lacking in any one of these aspects.

ITO, Kapton®, and EEONFELT all scored very well on uniformity. Kapton® and EEONFELT are both polymers, and therefore homogenous throughout. While the ITO layer is composed of discrete particles, those particles are on the nano-scale, and therefore not likely to introduce any gross irregularities in the material. Carbon fiber, on the other hand, is made to conduct by dopants added to the resin during manufacturing. Concerns that those dopants would be too big or not evenly disturbed are reflected in the low score received.

Several traits were taken into account when evaluating the heating characteristics of the material. First, the material had to be capable of reaching our target temperature of ~40° as well as withstanding such temperatures without suffering drastic changes in its mechanical properties. Second, it was desired that the heating element have low resistivity in order to minimize power usage. The scores received reflect our preliminary findings regarding the heating attributes of the materials.

As can be seen in Equation 1, thickness and density, along with the mass attenuation of the material, all play a role in determining radiolucency. Therefore, even though data on X-ray attenuation was not available for most of the materials investigated, either due to proprietary concerns or lack of manufacturer testing, we were able to evaluate the radiolucency of each candidate before ordering supplies for testing.

Finally, cost was taken into consideration. This semester we are working with a limited budget, hence any material must be (at the testing stage at least) relatively inexpensive. This category was not given more weight because it is not essential to the functionality of our design. Furthermore, should our design ever be mass-produced, any of the materials in question would be available at lower prices when purchased in bulk.

Based on the criteria considered above, ITO was identified as our target material and our design moved forward using ITO as our resistive heating element.

Final Design

The final design consists of four distinct layers. These layers, from the table surface to the patient, are: fine cell polyethylene pad, conductive Kapton RS®, ITO film, and a final layer of conductive Kapton RS®.

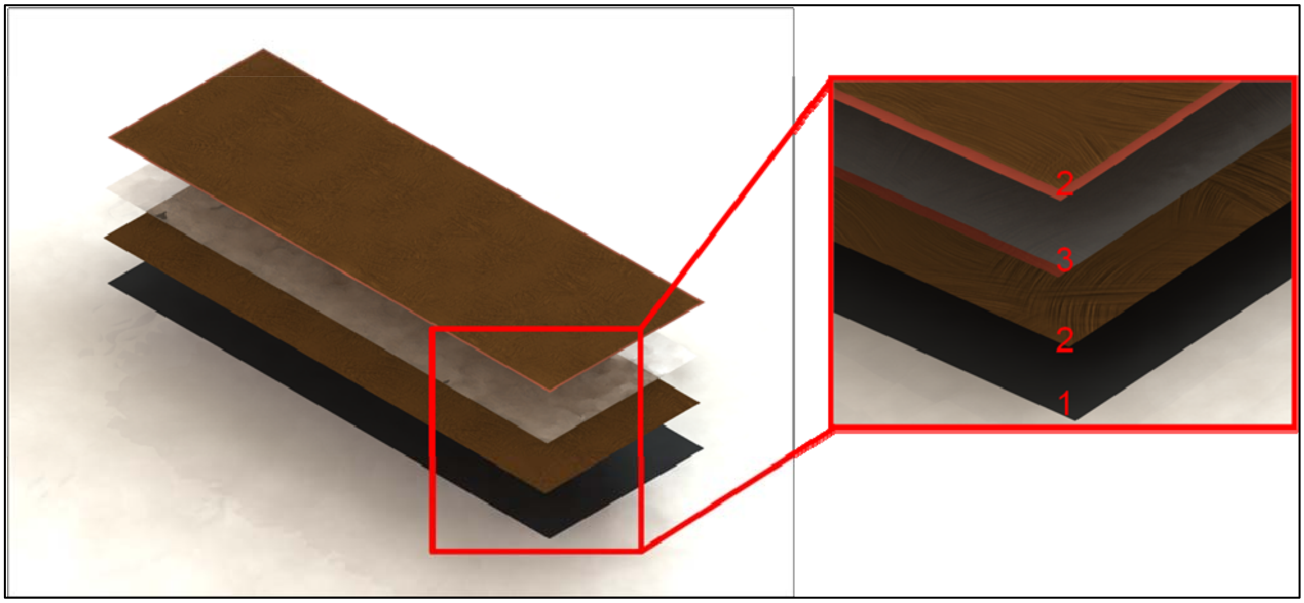

Figure 9: Exploded schematic of heating pad

The bottom layer, the fine cell polyethylene pad, serves two basic purposes: patient comfort and heat direction. The porous nature of the soft polyethylene foam provides a cushioned surface for the patient to lie on. Furthermore, the polyethylene foam is also an effective thermal insulator. This is a significant advantage, as it will direct the heat upwards, toward the patient, and reduce heat flux down into the table.

The second layer, the Kapton RS®, serves as an electrical insulator and safety mechanism. The Kapton RS® is oriented such that the conductive side is touching the polyethylene pad, while the insulating, dielectric side is touching the ITO film. The conductive side is electrically connected to earth ground, ensuring that if any charge or current were to make it past the insulating layer, it would be directly dissipated. Overall, the orientation and placement of this layer is a safety mechanism against patient electrocution.

The third layer, the ITO film, generates the heat. Voltage is supplied to this layer by busbars running along the length of the film. By connecting one busbar to the voltage source, and the other to ground, electrical current is passed through the width of the ITO layer. As current is passed through the ITO, energy is given off in the form of heat. This heat then flows to the patient.

The fourth layer, another sheet of Kapton RS®, serves the same purpose as the second layer. Once again, the Kapton RS® is oriented such that the dielectric side is touching the ITO film, and the electrically grounded side is facing upwards, towards the patient. As before, this is a safety mechanism to prevent patient electrocution.

Finally, all four layers are encased in a vinyl sheath. In addition to providing more electrical insulation, the vinyl surface can be easily sterilized between patient procedures. It also has the added benefit of being comfortable and aesthetically pleasing.

Indium Tin Oxide (ITO) Surface Heating

ITO is a transparent, conducting material and therefore can form a resistive heater distributed over the surface of the substrate while still allowing light to pass through. An ITO film of about 30 nm results in a resistance of 100 ohms/square (National Institute of Standards and Technology). The ITO film utilized in our design was obtained from Bayview Optics, Dover-Foxcroft, ME. Approximately 100 nm of indium tin oxide was deposited on a 0.0254 mm transparent polyethylene film to achieve a 60 ohm/square resistant sheet.

Kapton RS® Polyimide Film

Kapton® has been used in many applications including automotive, aerospace, consumer, and, most importantly, heating. Kapton® film has excellent thermal, electrical and mechanical properties. Because Kapton® films retain can withstand high temperatures (up to 350 degrees Celsius) they are ideal for use in extreme environments, especially as flat heaters. Because Kapton® is a completely organic materials, it contains mostly low molecular weight elements, making it radiolucent and ideal for X-ray imaging.

Kapton® is a .0508 mm (2 MIL) thick, bilayer polyimide film made commercially available by DuPont. One layer of the film, which is .0254 mm (~ 1 MIL) thick, is uniformly loaded with conducting carbon to produced tightly controlled surface resistance. The standard resistance of the conductive side of Kapton® is approximately 100 ohms/square. The other layer of the Kapton® film, which is also .0254 mm (~1 MIL) thick, has a 2,500 volt dielectric strength.

Kapton® has excellent mechanical properties and is durable under mechanical stress. Kapton® has a tensile strength of 131 MPa (19 Kpsi), a tensile modulus of 3.1 GPa (450 Kpsi) and exhibits up to 40% elongation before breaking. Because the conducting and insulating characteristics are distributed throughout the Kapton® material, instead of being coated on the surface, they cannot be cracked, rubbed off or damaged.

The weakness of Kapton® is its degradation. Kapton® cannot be exposed to humidity and ultraviolet light simultaneously without losing its mechanical and electric properties.

Busbars

It is important that we have good bus bar connections when applying voltage to our design. If electricity is applied non-uniformly through the bus bars to the ITO, dangerous "hot spots" can develop. To solve this problem we will use either a conductive ink or paint and screen press uniform bus bars, or we will mechanically clamp a metal bus bar to the ITO with a conductive paste at the interface. If mechanical clamping is used, it is essential that a non-curing conductive paste is placed at the interface to fill micro-gaps between the ITO and the bus bar.

Polyethylene Fine Cell Padding

Currently, it is not uncommon for radiologists to use pads manufactured specifically for the purpose of increasing patient comfort. Therefore, the use of padding to ameliorate the discomfort patients feel because of the hard examination surface is a concept that is already well established. When selecting a material for this component of our design, several factors were considered.

Fine-cell polyethylene (PET) was selected because previous testing had identified it as a good candidate for such use. In tests conducted last semester, our client identified fine-cell PET as the most radiolucent material tested, and most desirable for use in our design. The fine-cell PET pad is 3.2 mm thick – enough to make the X-ray exam surface soft and comfortable, but not so much as to distort the anatomy of the patient.

Furthermore, the layer of fine-cell PET serves to thermally insulate the bottom of the heating element, reducing heat loss in that direction and greatly increasing the efficiency of our design. Since the PET has a lower thermal conductivity than the table (which the heating element would otherwise rest on), the same temperature gradient generates a lesser heat flux, preventing heat from escaping into the table, instead directing it toward the patient.

In summary, the padding softens the stiff, unforgiving examination surface of the table and increases the efficiency of our heating design without introducing artifacts into the image or further attenuating the beam.

Vinyl Cover

Our design will utilize either a Nylon or Vinyl outer covering. These are common materials used for both exam tables and X-ray positioning pads. These materials are known to be radiolucent and are easily sterilized by ethanol and bleach solutions, common clinical sterilizing agents. When covering the inner components (i.e. ITO heater, Kapton, bus bars, thermistors, wires) it will be essential to make a seal to prevent any moisture from entering the device. Ideally, we would purchase a material with prior FDA approval, while taking cost into consideration.

Temperature Controlling Circuit

In order to include a degree of input and technician control, a circuit was included with the final design. The entire circuit is controlled by an ATMega8 microcontroller, which receives several inputs to determine appropriate output values.

The microcontroller receives input from four devices: three temperature sensors and one switch. The temperature sensors use +5V to read the surrounding temperature, and then output the temperature in terms of voltage. For this particular model, the LM35DZ, the output increases 10 mV for every degree Celsius. The outputs of all three temperature sensors are connected to three different pins on the microcontroller which, in turn, are connected to an internal analog to digital converter (ADC). The ADC converts the analog voltages to a digital value representing the temperature. The data from all three temperature sensors is averaged into one value, to be displayed to the user, and converted to degrees Fahrenheit. It should also be noted that the microcontroller is constantly receiving input from the temperature sensors, so the digital temperature values are updated almost immediately after any change in temperature. The other input, from the switch, is used to turn on the LED display.

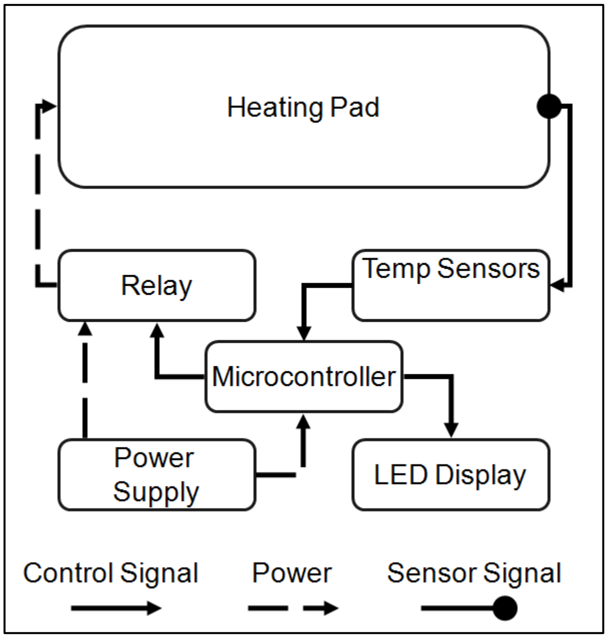

Figure 10: Block Diagram Circuit for Temperature Control

A majority of the outputs from the microcontroller connect to the LED display, which is used to display the averaged temperature. The LED display consists of four digits, each of which has seven segments. The first digit displays the hundreds digit of the temperature. If the temperature does not exceed 100 degrees, this digit is simply left blank. The second and third digits display the tens and ones place of the temperature, respectively. The fourth and final digit always displays a letter F, to indicate that the reading is in degrees Fahrenheit. The average temperature value itself is only displayed when a switch is pushed, to ensure that the digits do not change too rapidly for the user to read it accurately. It should also be noted that the LED display does not require power from an external source, as it is driven directly by the microcontroller.

The microcontroller is also connected to a relay, allowing it to shut off power to the heating pad. If, at any point, the temperature exceeds a pre-determined threshold, the microcontroller will send a pulse of current to the relay. This will cause the relay, which is also connected to the heating pad, to be “pulled”. When the relay is "pulled", it causes a switch to move within the relay, creating an open circuit between the voltage source and the heating pad.

Safety

As previously mentioned safety is of utmost importance in our design. Patients must be protected from the possibility of burns and electrocution.

Burns

Burns will be prevented by feedback from temperature sensors (thermistors) strategically placed in the device. Under normal function, the microcontroller on our control board will integrate these signals and maintain the chosen target temperature by powering the design on and off. Three sensors will be placed as shown in the figure below.

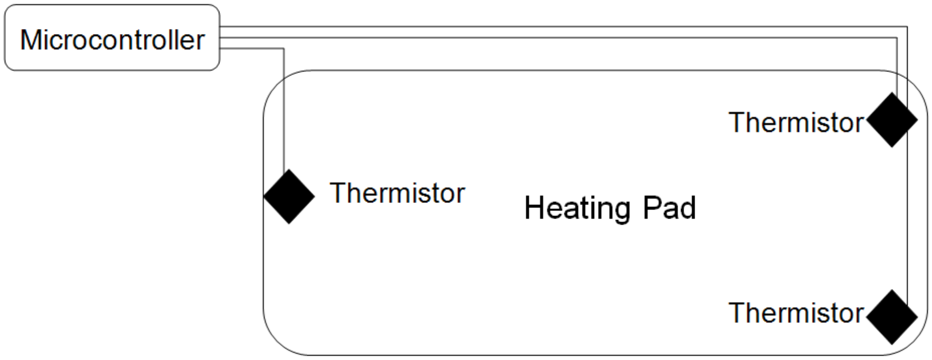

Figure 11: Temperature Sensor Locations

These sensors will be just below the vinyl cover yet above the Kapton film. Because they are metallic and radiopaque, they will not be directly below the patient. Instead they will be out of the imaging plane but still above the heated area of ITO. Because the patient will insulate the surface and cause for higher temperatures, testing will be performed to calibrate the temperature out of the imaging plane with the temperature directly below the patient.

In the event that the feedback from the thermistors fails, we will also incorporate either three thermal fuses or thermal switches. When a maximum temperature is reached, these fuses will break a circuit with the microcontroller, signaling it to stop providing power to the pad.

Electrocution

Electrocution will be prevented by several layers of electrical insulation. To begin with, the non-conducting, polyethylene side of the ITO film will be facing up towards the patient. On top of this, the dielectric side of a Kapton sheet will provide insulation up to 2,500 volts. The conducting side of the Kapton will then be grounded around its perimeter and catch any stray current that makes its way past the lower dielectric layer. Finally, the electrically insulating vinyl cover will insulate the grounded side of the conductive Kapton surface. This vinyl will also add safety by preventing moisture from entering the interior of the design.

Testing

ITO Heating Characterization

Resistive heating was achieved through the use of an indium tin oxide (ITO) film deposited on a transparent polyethylene substrate. Copper adhesive tape served as the busbar material. The resistive area was defined by the length and width of the ITO film contained within the busbar material. Total resistance of the heated area was theoretically calculated using Equation 2.

Equation 2.

$$R_T = \left(\frac{D_\perp}{D_\parallel}\right) \times R_s$$

Where R_T is the total resistance, $D_\perp$ and $D_{||}$ are the distances perpendicular and parallel to the busbars, respectively, and R_S is the resistance per square. The theoretical resistance per square was verified experimentally to the manufacturer's specifications by measuring the voltage and current across a $D_{||}$=10cm by $D_\perp$=5cm ITO film. Figure 12 illustrates the linear relationship between the current and voltage.

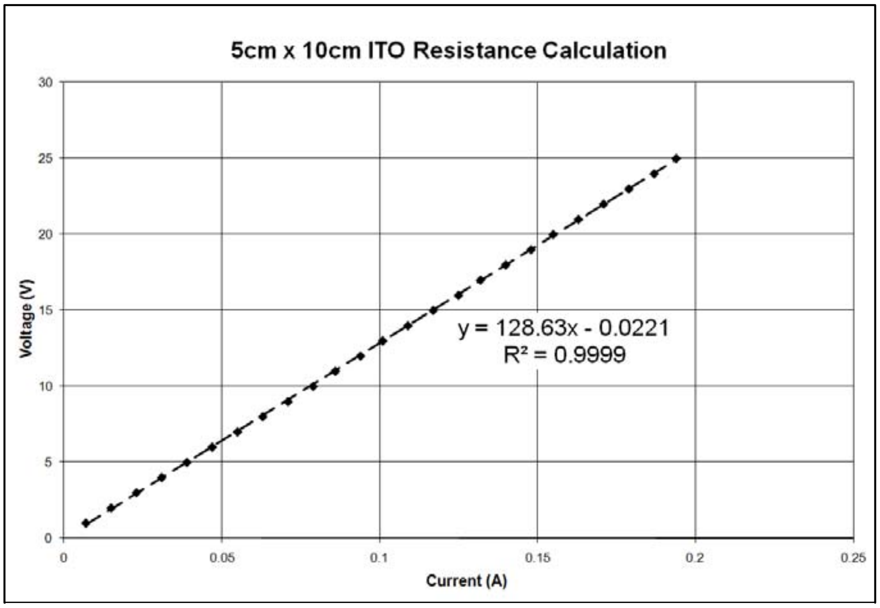

Figure 12: ITO Resistance Calculation. Total resistance (128.63 ohms) defined by the slope.

Using Equation 2, and the total resistance obtained in Figure 12, the ITO resistance per square was experimentally determined to be approximately 64 ohms/square. Therefore, the experimentally measured resistance per square agreed with the 60 ohm/square manufacturer's specifications.

ITO film temperature was measured using an infrared thermometer and all temperatures were obtained from the transparent polyethylene film surface opposite of the ITO layer. Temperature measurements were taken on the polyethylene surface opposite of the ITO layer because initial ITO temperature testing demonstrated that the surface opposite of the ITO layer exhibited a temperature approximately 5°C greater than the surface composed of the ITO layer.

ITO film temperature response was experimentally measure by applying, one after the other, constant 25 volt, 0.0 volt, and 25 volt DC electric potentials across a $D_{||}$=10cm by $D_{\perp}$=5cm ITO film for 5 minute intervals. The temperature of the polyethylene surface opposite of the ITO layer was measured at 10 second intervals for 12.5 minutes. Figure 13 illustrates the ITO temperature response. Steady state ITO film temperature was achieved in less than two (2) minutes.

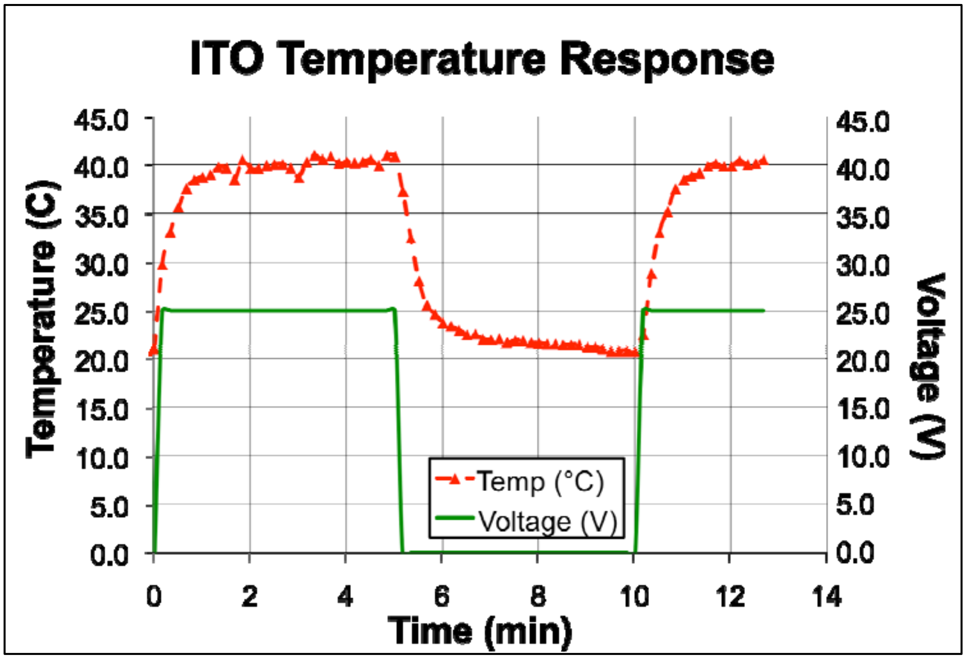

Figure 13: ITO Temperature Response

The relationship between ITO temperature and the power per area supplied to the ITO film was experimentally determined using an infrared thermometer. The temperature of the polyethylene surface opposite of the ITO layer was measured when a 15 volt DC potential was applied across a $D_{||}$=10 cm by $D_{\perp}$=5 cm ITO film. The corresponding current was recorded from the DC power supply and the resulting power per area was calculated accordingly. Only steady state temperatures were recorded and the procedure was repeated at 1 volt increments up to a maximum of 25 volts DC.

The relationship between prototype surface temperature and the power per area supplied to the ITO film was experimentally determined using an infrared thermometer. The temperature of the prototype surface was measured when an 11 volt DC potential was applied across a $D_\perp$=8cm by $D_\parallel$ =24cm ITO film. The corresponding current was recorded from the DC power supply and the resulting power per area was calculated accordingly. Only steady state temperatures were recorded and the procedure was repeated at 1 volt increments up to a maximum of 13 volts DC. Figure 14 illustrates the linear relationship between temperature and power per area for both the ITO film and Prototype.

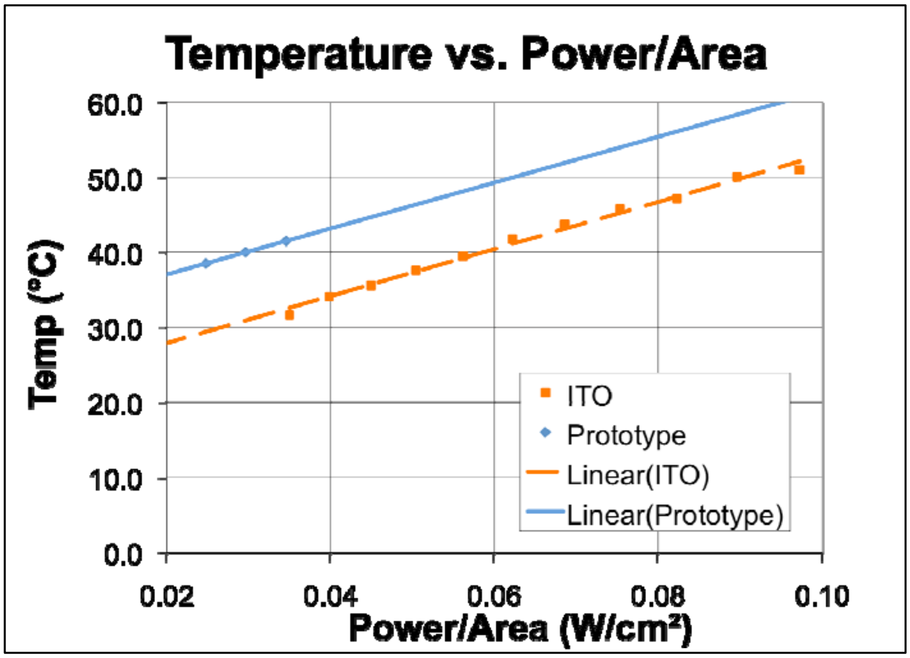

Figure 14: ITO and Prototype Temperature vs. Power/Area Relationship

Radiolucency

We first qualitatively assessed the components of our design for radiolucency. Testing with our client, we determined that the fine-cell PET, Kapton®, and ITO respectively were acceptable for use in our design. Tests showed that each material did not introduce artifacts, nor attenuate the beam unacceptably. While our client, an X-ray technician, generally approved the results, more rigorous testing was required.

In accordance with CFR-Federal Code of Regulations Title 21, our device may not attenuate more than the equivalent of 1 mm of Aluminum. To be sure of this, we quantified the attenuation of our fully assembled prototype. Using a program provided to us by the Department of Medical Physics, we determined that our device attenuated the X-ray beam by, at most, 3.9 percent. This compared favorably to the attenuation of aluminum, which was calculated to be about 4.5 percent using Equation 1 and standard values of density and mass attenuation for aluminum at 100 keV.

Figure 15: X-ray image of device and phantom. Although the busbars are visible, that was to be expected and will be accounted for by designing the device such that the busbars are outside the exposure field.

Figure 16: X-ray image used to quantify radiolucency. Notice how little the device (enclosed by busbars) attenuates the X-ray beam.

Again, the device was assessed qualitatively, this time using an X-ray phantom. Dr. Walter Peppler, a medical physics professor, determined that the image was acceptable for clinical diagnostics. Images used in the analysis are shown above (Figures 15 and 16).

Ergonomic Considerations

Human ergonomics is an important consideration when designing a heated radiologic exam table. A heated radiologic exam table should be constructed in a way such that any individual should be capable of understanding how it should be used. This requires the instructions to consist of figures and illustrations explaining the controls rather than the use of text. Also, not only should the design accommodate for individual differences in the user's ability to understand how the design should be used, it should also accommodate for differences in the users physical ability. Any knobs or controls on the device should be large enough so that any user, regardless of physical ability, can navigate the controls.

Future Work

Scale Up

Having built and characterized a functional prototype, we will build a full-scale version during the semester to come. During the design and construction of our prototype, we took several steps to ensure that the results achieved at the model level would be conserved when applied to a full-size device, approximately ten times bigger.

First, the aspect ratio (length : width) of our heating element is to remain constant in all iterations of our design. This ensures that the ratio of current to voltage remains constant for our circuit. While the magnitudes of current and voltage will certainly change, their proportions will not.

Second, conserving the power per area between devices ensures that we see similar heating profiles. By Forrier's law, two systems with the same physical characteristics (thermal conductivity and thickness) will see the same temperature gradient develop for a given power per area. It can be assumed that other physical characteristics affecting heat transfer (e.g. convection) will not be introduced, therefore identical power per area values should yield identical temperature profiles.

With these properties in mind, we carefully designed and constructed our prototype to have the same proportions as our final design. Simply by matching the aspect ratios, we are able to make certain that our prototype serves as an accurate model of our full-scale design in all aspects of electrical properties and heat transfer.

Circuit

We have constructed a basic circuit to power and control our heated diagnostic exam table. Nevertheless, a greater degree of control is required to fully meet our client's specifications. Next semester our work will center on implementing complete technician control over the device. Hardware and software enabling technician control is yet to be installed, however, we anticipate that most of our effort will have to be spent calibrating and validating those control mechanisms. For the safety protocols outlined above to be effective, it is imperative that we correctly interface the control and sensing elements of our circuit.

Conclusion

Our efforts over the last three months have led to a functional, albeit small-scale, prototype. The X-ray exam pad provides heat and comfort to the patient while preserving the integrity of the radiological image and minimizing the risk of injury by burn or electrocution. Our general approach has proven effective, and we are excited to continue with this project in the coming semester. Since we have answered many of the central questions regarding the nature and composition of our design, we will focus our efforts on optimizing the pad itself and adding features to our current circuit. By next May, we plan to have a full-sized device, suitable and ready for clinical use.

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Appendix: Product Design Specifications

Project Title:

Heated Diagnostic Radiology Exam Table

(Project Number: 38 / Project Code: exam_table)

Function:

Our team will develop a device to facilitate in X-ray imaging. A frequent patient complaint is that current X-ray tables are hard and cold. The device we create will supplement existing tables by increasing comfort through cushioning and heating. Any material or design used in the construction of our prototype must not interfere will the quality of images obtained when using the device.

Client requirements

Heated examination surface

Softer/cushioned examination surface

Must incorporate patient control

All materials must be radiolucent, no contrast can be introduced

No anatomical distortion

No obstruction of technician workspace

Uniform heating

No introduction of artifacts

Design requirements:

1. Physical and Operational Characteristics

Performance requirements: The device must be able to withstand continued use for up to ten hours at a time. The device must heat table surface to within +/- 5 C of 37 C. The device must be found comfortable by patients. The device must not interfere with X-ray imaging. The device will not be mechanical but of solid state design.

Safety: Care will have to be taken to make sure the patient is not at risk for burns, the table temperature may not exceed 50 C (skin burns at ~54 C). The device will be well insulated to prevent electrical shock. Voltage and currents will be kept at a safe level to avoid patient harm in the event of insulation failure. There must not be a magnetic field created by the device that could interfere with surrounding equipment or patient implants i.e. pacemakers/defibrillators. Regulations and guidelines for high voltage will be taken into high consideration. FDA certification may be required. We may have to submit a Section 2 - 510(k) Summary and Certification.

Accuracy and Reliability: Device must maintain a constant temperature whenever turned on (+/- 3 degrees farhenheit), as well as remain permanently radiolucent. The device will heat uniformly. The temperature of the device will be under patient control.

Life in Service: The device must have a life span of greater than 10 years. The need to replace the heating element or matting is acceptable assuming the cost of doing so is reasonable relative to the time needed between replacements (i.e. ~50$ per year in service).

S*helf Life*: The device must have a shelf life of greater than 20 years.

Operating Environment: The device must operate at a temp of 22°C and standard pressure. The device must not degrade in the presence of X ray radiation.

Ergonomics: The device fit on the top of a standard X-ray table, and should not have any rough edges.

Size: The device should fit within the table top dimensions of 87" X 31-3/4" (2.2 m X 8.8 m). Additionally, the device should be capable of allowing 45" (1.14 m) of longitudinal and 10" (.25 m) of transverse table movement. The device should work properly at a vertical position of 22" (.55 m) to 33" (.84 m). The size of the section of the device not on the exam table is not limited but should be minimized keep from obstructing the technicians work environment.

Weight: As stated in the user's manual, the maximum patient weight safely supported by the examination table is 350 lbs (158 kg). The device and the patient combined should not weigh more than this amount.

Materials: It is important that the materials used be radiolucent or transparent to X-ray. Inconsistency in the layout or depth of material may create unwanted attenuation/contrast to the X-ray. Testing has shown that tubing is not an acceptable material to use, the level of contrast introduced is too high. A uniform material is necessary with uniform heating capabilities. The surface of the device should be easily disinfected with mild bleach or ethanol solution to allow for many uses. Soft or awkward materials that may obscure or disorientate the body part being imaged are not acceptable.

Aesthetics, Appearance, and Finish: The goal of the product is to increase patient comfort; therefore, the appearance of the product should not be intimidating or provoke any fear or nervousness in the patient.

2. Production Characteristics

Quantity: Eventually, large scale production of the product may be needed to provide for hospitals.

Target Product Cost: The cost of the prototype must not exceed 1000 USD. The cost of the final manufactured heated examination pad would ideally not be more than 800 USD.

3. Miscellaneous

Standards and Specifications: The design and construction of the device must comply with the standards set by the client including the use of radiolucent materials.

Customers: Primarily the client, but can be potentially extended to any radiologist that looks to improve patient comfort during X-ray exams. Pediatric radiologists are prospective users of this device.

Patient-Related Concerns: The device must be sterilized before use with a different patient. It should not pose any burn related risks to the patients. There must be no chance of patient electrocution.

Competition: Current products do exist that increase patient comfort during medical exams but are limited by their price and functionality. Relatively inexpensive examination table pads exist but lack the potential to control the pad's temperature. On the other hand, multiple companies produce heated examination tables. However, these products are largely limited by their high price and X-ray compatibility.